

The NIH CATALYST

A PUBLICATION FOR NIH INTRAMURAL SCIENTISTS

NATIONAL INSTITUTES OF HEALTH ■ OFFICE OF THE DIRECTOR ■ FEBRUARY 22, 2005

The New Signals

On Outside Activities and Prizes:

WHAT YOU SHOULD:

- KEEP ON DOING
- GET APPROVED
- STOP DOING

by Celia Hooper

The long introduction preceding the Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements describes stringent restrictions intended as heavy-duty tarnish remover for NIH. Yet buried within the document are provisions aimed at another critical aspect of NIH's luster: encouraging NIH scientists to continue scholarly exchanges.

Six pages into the supplemental information, we read, "the Department is especially mindful of the need for substantive interaction within the scientific community." Later paragraphs also mention the importance of prizes, which "not only raise the visibility of the scientist, but also enhance the reputation of his or her institution and research area."

Behind these endorsements of scholarly exchange and recognition, the rules include tightly fitted provisions by which NIH staff can maintain academic vitality and remain active, contributing members of the larger community of scientists.

Outside Activities

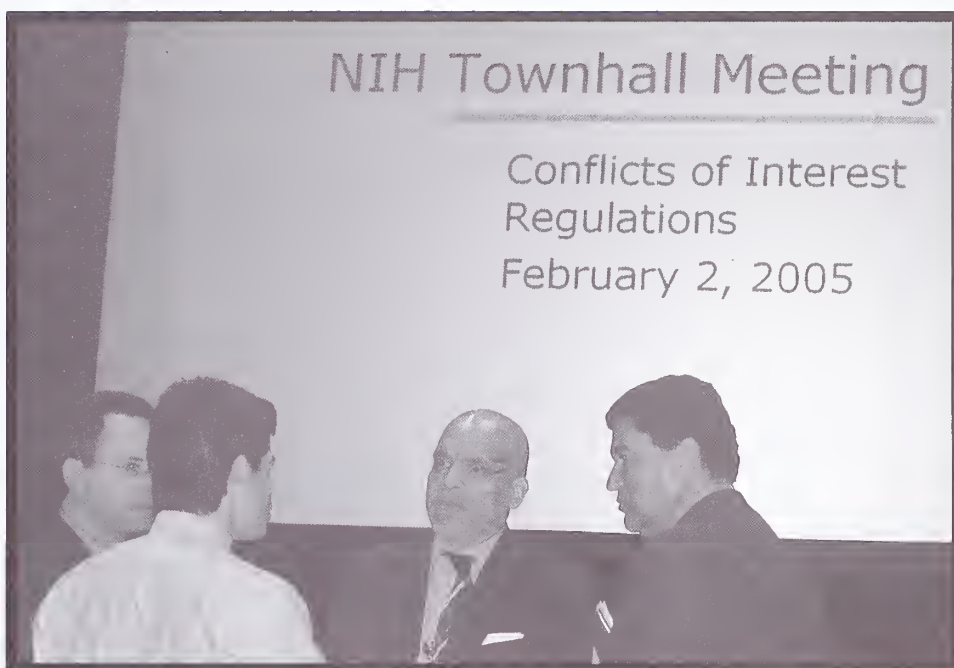
Traffic Advisory: Many of the specific rules of the road are still being worked on (see "What We Don't Know Yet," page 6), and more guidance—including specific procedures and deadlines—will be forthcoming in the weeks ahead. **The most critical step right now is to stop—or not start—any activities that are forbidden under the new rule (see "Road Closed" below).**

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Talk of the Town

NIH CONFLICT-OF-INTEREST REGS GENERATE IMPASSIONED GIVE-AND-TAKE

by Fran Pollner



Fran Pollner

Background: (left to right) John Burklow, NIH associate director for communications and public liaison, NIH Deputy Director Raynard Kington, and NIH Director Elias Zerhouni talk with Washington Post reporter Rick Weiss (back to camera) on the occasion of the Town Hall meeting and the regulations that occasioned it

The crowd at the all-hands NIH Town Hall meeting occasionally burst into ironic laughter—like when the scientists were reassured that they could probably still accept a Nobel Prize and not violate the new federal regulations on "Standards of Ethical Conduct and Financial Disclosure Requirements" for NIH employees.

For the most part, however, the mood was somber and the participants perplexed. NIH leadership had given the NIH community a heads-up on the general content of the new regulations—which would be effective immediately upon publication in the *Federal Register* the next day, February 3, and which would circumscribe the outside activi-

ties, awards, and stock holdings of NIH employees.

NIH Director Elias Zerhouni, NIH Deputy Director Raynard Kington, and NIH Ethics Office Director Holli Beckerman Jaffe variously explained the

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GUIDING PRINCIPLES



Elias Zerhouni

Conflict-of-interest issues and other divisive vital issues have tugged at the fabric of the NIH community before, but within my time so far at NIH, there has been no more divisive issue for NIH staff. I have taken a strong position to protect the credibility of NIH science, and I know many of you appreciate the importance of this issue for NIH and for the country as well.

This unprecedented dedicated issue of *The NIH Catalyst* seeks to clarify the new conflict-of-interest rules; this editorial expresses my heartfelt hope that increased understanding will reduce the stresses and strains and patch up any holes that may be emerging in our community as we restore public trust in NIH.

Where do we start? The first step is in understanding what the new Interim Final Rule says. On these pages, the rules are again summarized, but not from the standpoint of the lawyers. This time we're highlighting the good news: that the important academic exchanges that traditionally informed our science can and should continue.

We also repeat what you cannot do and what things are still being worked out. We highlight how you can register your opinions about the regulations to help improve them and how you can seek exceptions when you believe that your personal situation offers a compelling reason to exempt you from specific conflict-of-interest regulations.

It is important to understand the precepts that stand behind the conflict-of-interest rules. They are:

1—You must not “serve two masters.” You cannot have another financial interest in the work that you do for NIH outside of your federal job.

2—You must not “double-dip.” If the taxpayers have paid for your work, someone else may not pay you again for that work.

3—Within the boundaries of the first two rules, it is important to protect your rights to speak and write so as to guarantee that biomedical research remains a free marketplace of ideas and constructive interactions untainted by bias and conflicts.

As we begin implementing the conflict-of-interest rules, the challenge for administrators will be to assure that the policies are clear and understandable, that they are fair and consistent, and that their implementation is efficient. If the review of official duty activities is cumbersome and time-consuming, this could stifle collaboration almost as much as a ban.

Amidst all the chaos and noise from the new rules, my last exhortation is not to become deaf to your own inner judgment. This has been and always will be the most important fiber in the integrity of our community. If something sounds wrong to you, if it feels uncomfortable, don't do it—whether the rules cover it or not. Rules and lawyers can't cover everything, but our fundamental good judgment can.

Finally, as we emerge from this painful episode, I remain just as concerned about the necessity to protect the vitality of our precious intramural program as about the need to close this unfortunate chapter in our history. I want to encourage a wide, direct, and open dialogue with all of NIH's staff to carefully evaluate these interim final rules during the official comment period for any unintended consequences or undue hardships—which I will do my best to address. This is why I encourage all of our community to participate in a forthright and constructive process to insure that we learn from the events of the past and develop a more transparent and responsive system that will reestablish the moral authority of NIH while preserving the excellence of our science.

—Elias Zerhouni
Director, NIH

A GUIDE TO PREVENTING CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH AT NIH

This guide was issued by the deputy director for intramural research (DDIR) January 4, 2005, and sent to all IC directors, scientific and clinical directors, and OD staff. A work in progress for several years, the guide specifically addresses potential conflict of interest and receipt of payments for NIH inventions in the context of clinical research and complements the NIH conflict of interest regulations that took effect February 3.

Avoiding financial and other conflicts of interest is important for NIH, where the trust and protection of research subjects is vital to our mission to improve the public health. The number and complexity of laws and regulations in this area makes it difficult to know when there is a problem and what to do. This guide is intended to assist clinical investigators in avoiding real or perceived conflicts of financial and other interest.

I. What are a clinical investigator's potential conflicts of interest?

All clinical investigators have primary obligations. These include obtaining knowledge that will promote health and health care and helping ensure the safety and health of research participants. Clinical investigators may also have other personal or secondary interests, which could include teaching trainees, supporting a family, and earning income. These secondary interests are not, themselves, unethical, but in some circumstances, they have the potential to compromise, or appear to compromise, the judgment of clinical researchers regarding their primary obligations. When these secondary interests compromise judgment, or appear to do so, there is a conflict between the secondary and primary interests.

This guide provides information to prevent financial and other conflict, thereby helping to ensure both the integrity of our research and the safety of participants.

II. To whom does the guide apply?

This specific guide applies to all investigators who substantively participate in the development, conduct, or analysis of clinical research protocols, both diagnostic and therapeutic, and are listed as investigators on the front sheet of protocols.

In particular the guide applies to:

- Principal Investigators
- Associate Investigators—that is, all persons whose names appear on the front sheet of a protocol. NIH regards an "investigator" to be the principal investigator and any other person who is responsible for the design, conduct, analysis, or reporting of research funded by the DHHS. In addition to his or her own financial interests and outside interests (see Section III, below), an investigator's financial interests also include the financial interests of others such as his or her spouse, dependent children, or household members, and

any outside entity or foundation in which any of these persons have a financial or other interest that could be directly affected by the conduct of the research.

III. Conflict examples:

- Serving as a director, officer, or other decision-maker for a commercial sponsor of the human subjects research

- Holding any stock or stock options in a commercial sponsor of the human subjects research (unless held in a diversified, independently managed mutual fund)

- Receiving compensation for service as consultant or advisor to a commercial sponsor of the human subjects research (excluding expenses)

- Receiving honoraria from a commercial sponsor of the human subjects research

- Personally accepting payment from the human subjects research sponsor for nonresearch travel or gifts (government receipt of in-kind, research-related travel is not included)

- Obtaining royalties or being personally named as an inventor on patents (or invention reports) for the product(s) being evaluated in the human subjects research or products that could benefit from the human subjects research (special rules apply in this case when NIH holds the patent—see below)

- Receiving payments based on the research outcomes

- Having other personal or outside relationships with commercial sponsors of the human subjects research*

- Having financial interest in companies with similar products known to the investigator to be competing with the product under study.

IV. How it works

NIH has established a system to assist in identifying and preventing financial conflicts for investigators in clinical research:

The PI is responsible for assuring that each investigator listed on the protocol front sheet receive a copy of the guide. Any investigator who has a potential conflict must inform the PI of the conflict and how they plan to eliminate this conflict, consult with his or her IC deputy ethics counselor to determine how to resolve any actual or apparent conflict, and then report back to the PI on the plan to eliminate the conflict.

- In ProtoType (see *The NIH Catalyst*, November-December 2003, page 7) or in a short memo accompanying the protocol, the PI will answer the question as to whether the guide was provided to each

investigator on the protocol and whether any conflict of interest was identified for the protocol as a whole. If no, then nothing need be done. If yes, the PI will describe what the conflict was and how it was eliminated. This will take place at the time of initial and continuing review.

- The clinical director who signs the protocol document will thus be aware of the PI's answer(s), and the IRB will also receive a copy of the disclosure for the protocol as a whole at the time of the initial and continuing reviews.

- The DDIR will receive a quarterly report (generated from ProtoType) of any conflicts of interests and how they were eliminated without reference to specific individuals.

- The PI is required to distribute the guide to all investigators and update each protocol at the next continuing review based on comments received from the investigators.

V. How will NIH intellectual property and royalties be handled?

In some instances, NIH clinical research protocols will evaluate or potentially advance product(s) in which NIH (that is, the government) owns patents or has filed invention reports. In such cases:

- An NIH investigator may participate in the clinical trial, even if the investigator is listed on the patent or invention report and/or may receive royalty payments from the product(s) being tested.

- When such an investigator participates in a trial, there should be full disclosure of the relationship to the IRB and to the research subjects (that is, information should appear in the consent form) with review and approval by the IRB.

- In the case of continuing review of current protocols where NIH has an intellectual property interest in the invention, investigators should provide a new human subjects consent form or correspondence outlining the relationship, for review and approval by the IRB.

- An independent entity, such as a DSMB, must review the results of all such human subjects research.

- These relationships must be reported to the DDIR as part of the quarterly report, without reference to specific individuals, but should not impede the pursuit of the trial. This will be done via ProtoType. ■

** Employees are reminded that applicable authorities prohibit them from having, for instance, outside activities, gifts, or other forms of compensation from outside entities that are related to the performance of official duties from/with commercial sponsors of clinical research in which they participate.*

If you need to request a time extension to wrap up a now-banned commitment, you must make this request in writing to your ethics officer by **March 5, 2005. You will be in violation of the rules if you fail to submit a request and persist in the activity.**

Yield sign: While other rules or your supervisor may not allow you to proceed, the new rule offers the greatest freedom for official duty activities. These are interactions that NIH staff may pursue—with a supervisor's approval—as part of their NIH duties because they benefit NIH. Once approved—and without any compensation beyond your regular government paycheck—you may:

- Present your research at a scientific conference

- Conduct a site visit

- Serve on editorial or professional society boards (**note:** you may need some special waivers, and you cannot have fiduciary responsibilities in the outside organization)

- Give a lecture or workshop on your research at a company, university, or nonprofit institute

- Exchange research materials

- Collaborate

- Participate in a CRADA

- Teach a course

- Edit publications

- Hold a patent and receive royalties from an invention that arose from NIH work

To encourage scientists to pursue these uncompensated official duty activities, the rules say the NIH administration will strive to accommodate speaking activities "that might previously have been considered less directly connected to agency mission." Travel reimbursement from your host is permitted. The NIH Office of Financial Management is reviewing NIH-wide guidance on "348" travel.

Scenic highway: Of course, the rules also allow you the freedom to be an unpaid volunteer in your free time in areas outside NIH's purview. You may teach, speak, write, edit, or otherwise serve in a political, religious, social, fraternal, or recreational organization.

You may accept reimbursement of expenses for this work. You don't need approval from NIH—unless you are providing professional services (such as legal, accounting, or medical services) or are getting compensation beyond reimbursement of expenses.

Stop sign: If you want to engage in an outside scientific activity, **you will first need to stop and request and receive approval from your ethics official.** While procedures are still being worked out, you should allow plenty of time for this.

As a general guide, your request to do an outside activity will be denied if it would mean you would have to disqualify yourself from your work duties because of resulting conflicts. They will also turn down activities that would violate statutes, including those that prohibit using your government position for private gain (see "Guiding Principles," page 2).

But within those bounds, there are a number of compensated outside activities that the rule says can be performed with prior approval.

For the most part, these are activities that help scientists maintain their skills, credentials, and professional reputation. If it doesn't conflict with NIH responsibilities or significantly overlap with your NIH work, your ethics officer can approve:

- Teaching a course (including in your field) that is part of a school's regular curriculum

- Providing medical, dental, nursing, or pharmaceutical treatment of patients

- Writing or editing a peer-reviewed scientific publication—provided the funds don't come from an inappropriate source

- Teaching or moderating an accredited CME or CME-type course—again provided the funds don't come from a biasing source

- Moonlighting in clerical, retail, janitorial, and other nonprofessional jobs

When he or she reviews your request for permission for these outside activities, your ethics officer will look closely at the particulars to be sure there is no conflict or appearance of conflict between the activity and your NIH responsibilities. Approvals are granted only for one year—you have to reapply every 12 months to continue with an ongoing activity.

Get your license: **Everyone must file a report on all outside activities—whether or not you had previous approval for them—by April 29, 2005. The annual reporting date in future years will be February 28.**

Road closed: With the exception of the "stop sign" activities above, you can't perform an outside activity for an orga-

nization that is materially affected by NIH's work.

These prohibited organizations include biotech and pharmaceutical companies (and other companies involved in research, development, or manufacture of medical devices, equipment, treatments, or other products), NIH grantee institutions and contractors, health care providers or insurers, trade or professional organizations, and nonprofit health lobbying groups. A preliminary list of "prohibited organizations" is being prepared and will be available through a link from the NIH Ethics page:

<http://www.nih.gov/about/ethics_COI.htm>

"Outside activity" includes any type of employment or business relationship where you provide a service, including consulting, serving on a board, paid teaching, speaking, writing, or editing. You also can't be a self-employed sales agent or advertiser for one of these prohibited organizations.

You have until **March 5** to end any "road-closed" relationships, although if you need more time to exit, you can request a 60-day extension in writing from your ethics office. **You have to submit your extension request before March 5.**

Prizes

Narrow bridge: As always, the new rules pertain only to awards for what you do as a government worker and awards that come from organizations that are affected by NIH. So, go ahead, claim your bowling team's trophy for the most gutter balls, or that blue ribbon for prize dahlias at the county fair. Your church gave you a potted plant for filling in for the choir director when she had a baby—no problem!

Stop sign: Unless you are a senior employee (see below), you can, *with prior approval from your ethics office*:

- Accept a prize or gift of \$200 or less

- Accept one of the prescreened prizes and awards for scientific achievement or meritorious public service

A preliminary list of potentially approvable prizes endorsed by the Advisory Committee to the Director will be available through a link from the NIH Ethics page:

<http://www.nih.gov/about/ethics_COI.htm>

You must get approval in advance to receive the award. You won't be allowed

to accept the award if it comes from an organization that has applications, grants, research collaborations, CRADAs, or other matters that have been or might in the future come before you or someone who reports to you.

For a year after you accept the award, you cannot be involved in any business that involves the award donor. If you fail to get prior approval for an award or accept a prohibited award, you could be required to forfeit or return the award, have it removed from your CV, and suffer other administrative discipline.

No entrance: Senior employees are prohibited from accepting an award worth more than \$200 from any entity that has dealings with NIH. This includes anyone who might seek to do business with NIH, file a grant application, or be engaged in activities that are significantly affected by what NIH does.

Senior employees include the NIH director, directors of the institutes and centers, and anyone who reports directly to the directors (deputy directors, scientific directors, clinical directors, and extramural program officials). Other people who have equivalent levels of responsibility or who are designated as "senior" also fall under this tighter prohibition.

Entrance by special permit only—Or maybe we should call this the Fond-est Dream Exception: Senior officials can apply for an exception to receive competitive prizes worth more than \$200. Such exceptions would probably be granted for "very prestigious awards such as the Nobel Prize and the Lasker Award. . . ." See ya in Stockholm!

Stock Holdings

The new rules on stock ownership are perhaps the most unexpected part of the new rules. The rule's preliminary information says the changes spring from growing influence of NIH on medical research and the industries based on it. Also mentioned are the complex and rapidly changing interrelationships of companies today and the difficulty of evaluating the potential influence of each scientist's work on industry and vice versa. At the NIH Town Meeting (see p. 1) NIH Deputy Director Raynard Kington said simply, "The world has changed."

Specific concerns that are mentioned are that ownership of stock "would cause a reasonable person to question the impartiality or objectivity with which NIH programs are administered," and that

NIH staff might make investments based on information that was not publicly available.

Caution! As this special issue of *The NIH Catalyst* goes to press, **NIH ethics officials are strongly urging people NOT to divest their stocks yet.** Please watch for further information as they work out more details on specific procedures, exceptions, and deadlines.

Another key point is that if you are required to divest and would incur a capital gains tax from that, you may apply for a certificate of divestiture that permits you to trade your prohibited investment for an allowed asset and defer the tax until you sell the new asset. You must apply for this certificate **before** you trade the stock. **All NIH employees will be required to report on ownership of restricted stocks by April 4. Please watch for further information on how, what, when, and where to report.**

Green light: All NIH staff may own any amount of broadly based mutual funds and individual stocks that are not in NIH-related companies—provided the stock ownership doesn't conflict with official duties. NIH is developing a list of restricted stocks (see below).

If you came to NIH from a previous job in industry and you or your spouse or child (under age 18) have a benefits portfolio from that job that includes biotech or pharmaceutical stocks, you may be able to keep the stock.

If your spouse is working for a biotech or pharmaceutical company and receiving stock as a result, he or she may continue to hold the job and likely the stock. (The NIH spouse would not be allowed any responsibilities at NIH that involved the spouse's employer, of course.)

Vehicle weight limits ahead: Mutual funds emphasizing biomedically related stocks ("sector funds") and stocks on the restricted list are limited for some NIHers and completely disallowed for others. Stocks on the restricted list will likely include:

- Pharmaceutical companies
- Biotech companies
- Medical device companies
- Research companies that develop medical or healthcare products
- Biomedical research companies
- Health care providers
- Health insurance companies

■ Companies providing biostatistical services

■ Companies conducting behavioral or psychological research

NIHers who are "nonfilers," that is, who do NOT file financial disclosure forms (SF278 or OGE Form 450) are in the limited category. They, their spouse, and their children under age 18 together may invest up to \$15,000 in any stocks on the restricted list.

There is no limit on the total number of stocks nonfilers may invest in, but the total holdings of restricted stocks must account for less than half of the total of the family's combined investment portfolio. In addition, the family's combined holdings in a company must constitute less than 1 percent of the total outstanding equity of a company.

The \$15,000 "*de minimis*" level of holdings is based on the value of the stock when the market closed on February 3, 2005, providing you meet the *de minimis* test during the transition period. You don't have to divest of shares if the stock increases in value after February 3, and the \$15,000 limit will go up if the government-wide *de minimis* level is raised.

Stop and turn back: NIH employees and their spouses and minor children who file either the public disclosure or the confidential disclosure forms ("filers") may not own stocks on the restricted list, unless an exception applies. Filers must report these stock holdings by 60 days from the time the rule went into effect, and then have 90 days from that time to divest of all prohibited stocks. Extensions to both of these deadlines may be granted.

Possible detours: The rules open a few exceptions permitting some staff that would otherwise be disallowed from holding any banned stock to hold *de minimis* levels:

■ NIH ethics officials are studying whether some groups of NIH staff, such as purchasing agents who are "filers" because of their procurement responsibilities, may be counted as "nonfilers" when it comes to stock holdings.

■ Under "exceptional circumstances," the NIH Director and DHHS ethics officials may grant an individual a written exception to the rule on stock holdings, provided the exception would not be illegal or undermine public confidence in NIH objectivity. More guidance on how to submit a request will be out soon. ■

TALK OF THE TOWN

continued from page 1

rationale and intention of the "interim final rule" and the meaning and implications of specific provisions. But there were questions that remained unanswered and objections that were not mollified.

The perception of conflicts of interest, the actual failure of some scientists to disclose financial arrangements, and the need for uniform reporting procedures throughout NIH culminated, Zerhouni said, in the DHHS-promulgated rule—a raft of pages of regulatory language that might be arcane in places but reflected decisions that "had to be made."

"Our number-one priority," Zerhouni said, is preserving the public trust and continuing to be seen "as the ultimate source of unbiased scientific information." He rued the "actions of a few" that had compromised the perceived integrity of NIH, the inspired work of so many thousands of NIH scientists over the years, the increasingly critical and valuable NIH collaborations with industry, and the continuing ability of NIH to recruit and retain the finest scientific minds.

After hearing a brief rundown on the new regs, those members of the audience who spoke at the mikes protested the harshness and seeming unfairness of many of the provisions. They expressed fears that following the rules would undermine the collegial exchange of vital information that leads to biomedical advances and would prohibit their continuing to engage in some of their most intellectually rewarding outside work (for an in-depth interpretation of what can and cannot be done under the new rules, see "The New Signals," page 1). Some decried the across-the-board punitive nature of the NIH-targeted stock-holding regs—especially for NIH trainees and others who are here for a short term only. Recruitment, several speakers maintained, would be undermined.

Said one branch chief: "I can see some of these requirements as a precondition of hiring, but here the rules are being changed midstream and can cause irreparable financial harm."

Said a PI: "I can understand the stringencies placed on consulting arrangements. But where is the conflict of interest in investments? What's the rationale? We're not a regulatory agency. Do these rules apply to ALL the employees of HHS, or only NIH? Do they apply to the Department of Defense?"

Said a department director: "Do these rules apply to everyone who gets an NIH grant? And just what is a conflict of interest? Having more than one interest doesn't mean a conflict of interest unless those interests are in conflict!"

"The investment restrictions are clearly punitive to NIH employees," another speaker said. "Our outside advisors are not subject to this—not the people from industry and the universities who sit on our councils and study sections . . ."

Said another, "How can the U.S. government in the year 2005 ask spouses to give up holdings so their spouse can maintain their NIH job? Spouses are independent people . . . the ACLU is quite interested in this."

The meeting went on for nearly two hours. Some attendees were reassured that their favorite activities were not only permissible but desirable; others remained frustrated. Zerhouni exhorted the community to respond to the *Federal Register* rule within the allotted 60 days. He also said that NIH would be examining whether the new rules were having any "unintended consequences"—such as adverse effects on recruiting and on NIH's mission to provide for the common good. ■



Celia Hooper

Holli Beckerman Jaffe
Director, NIH Ethics Office

What We Don't Know Yet**UNDER CONSTRUCTION: BEAR WITH US**

As you know, the new rules set deadlines. The time for compliance with some of the provisions draws near. However, some employees may be unable to fulfill their obligations under the regulations because there are implementation questions unanswered and necessary procedures yet to be established. Please continue to be patient. We are working as quickly as possible to get answers, to make the rules clear and understandable, and to make their implementation fair and efficient. Here are the most critical details we are working out as *The NIH Catalyst* goes to press:

The application of the rules to various members of the NIH community. Certain classes of NIHers may be exempt from the total prohibited holding ban or may be switched from the total ban to the *de minimis* rule.

When the stock divestiture period will begin. Right now, it's set for April 5, but an extension of the filing date for the supplemental disclosure reports may be issued. If this happens, it will also push back the start of the divestiture period.

The breadth of the definition of "substantially affected organization (SAO)." The definition says that an SAO is an entity that is "significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products." But "significantly involved" still needs to be interpreted.

How employees should report the information required by the new rules. We are revising and developing some new forms and will distribute these shortly, along with instructions for their use.

Specific operating procedures. There are numerous procedural provisions in the regulations, several of which allow employees to ask for extensions, exemptions, exceptions, or waivers of the application of the rules. For now, employees should file any such requests with their IC ethics office.

As we get answers, procedures, or changes in the COI policies, we will send out NIH-Staff-list messages and post the updates through a link on the NIH Ethics page:

<http://w.ww.nih.gov/about/ethics_COI.htm>

—NIH Office of Intramural Research

WHERE TO SEND YOUR COMMENTS

The NIH community may be able to have an impact on whether and how the rules are changed. Anyone interested in expressing their views can communicate with NIH leadership and federal regulators at the addresses below.

■ To respond to the federal regulators regarding the February 3 *Federal Register* regulation, comments **must be submitted by April 4, 2005.**

Write to: Office of the General Counsel, Ethics Division, DHHS, Room 700-E, Hubert H. Humphrey Bldg., 200 Independence Ave. SW, Washington, DC 20201, Attn. Linda L. Conte

Or e-mail: **<<mailto:ethics@hhs.gov>>**. Important: The subject line should include: "Comments on Interim Final HHS Supplemental Ethics Rule."

■ To contact NIH leadership:

<<mailto:Conflictofinterest@od.nih.gov>>.

Important: The subject line should begin with: "Question:" or "Comment:" Note that this address is accessible to individuals outside NIH. ■

STATEMENTS FROM SOME NIH SCIENTISTS

THE ASSEMBLY OF SCIENTISTS

The Assembly of Scientists believes there must be secure safeguards to ensure that financial interests do not compromise the design of research, the safety and well-being of patients, the collection and interpretation of research data, and the dissemination of research results, as well as funding and contract decisions. Strong restrictions on financial interests are necessary to protect the public trust in and the integrity and professionalism of the NIH and its staff. However, the DHHS supplemental regulations substantially overreach and will severely and irreparably compromise the NIH's mission.

These new regulations will discourage talented, innovative scientists from staying at or being recruited to the NIH, and preclude scientists already at the NIH from participating as full members of the scientific community.

They will prohibit some outside activities by NIH employees with a wide variety of organizations that present no possible conflicts of interest. The restrictions on outside activities do not just apply to pharmaceuti-

cal companies, but could also inhibit interactions with scientists and others at universities, professional societies, and advocacy groups where the exchange cannot be approved as an official duty activity or as one of the permitted outside activities. Such barriers could make it harder to effectively and efficiently translate discoveries into therapies.

In addition, these regulations prohibit nearly 40% of NIH employees, their spouses and their children, including many who have no decision-making authority for grants or research, from holding any equity in any company that produces or sells pharmaceuticals, biotechnology products, or medical devices and could be extended to include food or beverage companies if NIH conducts coordinated research on obesity. They also limit the families of all other NIH employees, including secretaries, food handlers, elevator operators, lab technicians, electricians and others—clearly employees who cannot have relevant conflicts of interest—from holding more than \$15,000 in these companies. Such expansive restrictions seem unnecessary and unlinked to preventing con-

licts of interest, but they will have profoundly detrimental financial impacts on individual employees and hinder recruitment and retention.

More carefully crafted regulations that prohibit financial conflicts of employees who have decision-making authority and responsibility for the scientific direction of NIH, funding decisions, and grants management, and who conduct research can provide secure safeguards while promoting NIH's mission of scientific advancement.

To ensure the NIH can continue to be a great research institution, the Assembly of Scientists is developing alternative proposals and exploring appropriate action to change these regulations. NIH employees interested in learning about the Assembly of Scientists' activities in this area should contact one of the elected members of the Assembly's Executive Committee. There is also a web site that will soon post additional information:

<<http://homepage.mac.com/assemblyofscientists/>>.

We welcome all suggestions.

—The Executive Committee:

Harvey Alter (CC), Karen Berman (NIMH), Cynthia Dunbar (NHLBI), Ezekiel Emanuel (CC), Lee Helman (NCI), Steven Holland (NIAID), Elaine Jaffe (NCI), Hynda Kleinman (NIDCR), Edward Korn (NHLBI), Steven Libutti (NCI), William Paul (NIAID), Donald Rosenstein (NIMH), Alan Schechter (NIDDK), Earl Stadtman (NHLBI), Melanie Vacchio (NCI), Lauren Wood (NCI), Kenneth Yamada (NIDCR), Howard Young (NCI)

THE FELLOWS COMMITTEE

Excerpts from the letter to to Michael Gottesman and Elias Zerhouni from the NIH Fellows Committee, representing more than 3,000 fellows at NIH.

NIH postdoctoral and clinical training programs attract highly qualified and motivated fellows. . . . It is imperative for the health of biomedical science and the nation that these productive, but temporary, researchers continue to be recruited and maintained at the NIH. . . . We are concerned that the proposed conflict-of-interest regulations will have an unanticipated and adverse effect on both current and future fellows. Our main issues of concern are as follows:

Conflict of Interest as defined in the current environment applies primarily to staff with the capacity to influence policy, stock prices, or public health matters. Like our peers in NIH funded extramural programs, NIH trainees do not have the same capacity for influence as do the permanent senior scientists and therefore it is unreasonable to hold them to the same level of scrutiny. By nature of the training position, fellows are supervised by senior staff and do not control any resources. We propose an exemption to these measures for trainees or, alternatively, regulations that better reflect their limited capacity for influence.

Trainees are often not considered em-

ployees for such positive benefits but could be held to the same restrictive standards as employees with full benefits. Indeed the majority of fellows (IRTA and CRTA) are not considered employees and do not qualify for Loan Repayment Program, Health Insurance, or Social Security Benefits. We suggest a separate category for trainees or at least consistency in the manner of determining who is an employee and who is not.

Regulations prohibiting biotech stock holdings for spouses and minor children will negatively impact recruitment of high quality fellows. The effectiveness and reputation of the NIH programs depend on its continued ability to recruit and support excellent trainees. Such applicants have many other prestigious options for training programs that do not have such restrictions. Scientists coming from industry may find this regulation particularly punitive. While a \$15,000 limit will apply to many fellows, significant numbers of fellows have been asked to file Form 450 and will be subject to divestiture of all their holdings. Again, such problems could be solved with a separate category for trainees.

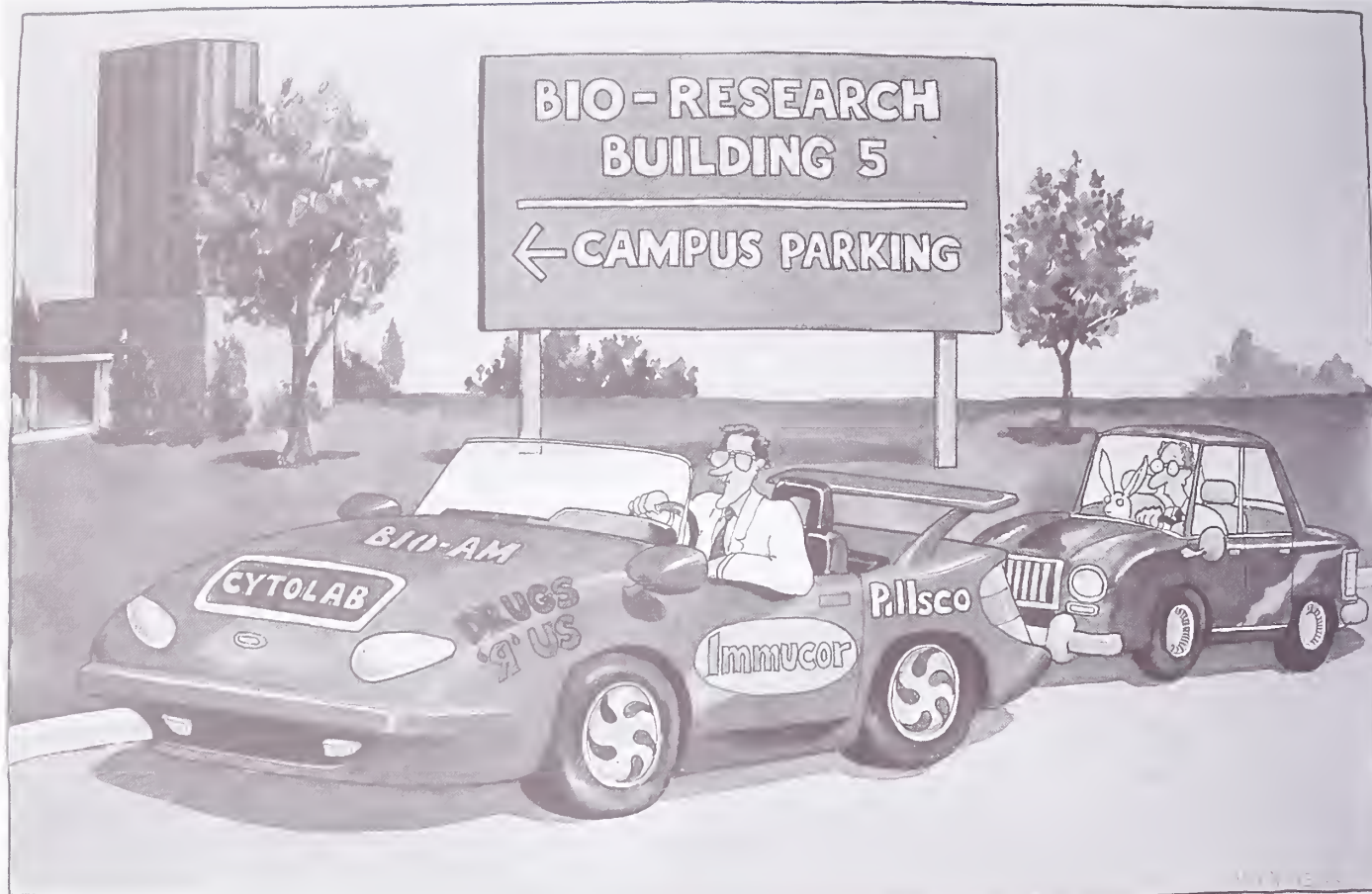
Proposed limitation of awards to approved listing of specific awards. Travel awards to conferences, workshops, and other professional development activities for fellows are an important means for career

development and offset some of the costs incurred by the NIH for fellows to present data at national and international meetings. As proposed, the establishment and maintenance of a useful approved award list would be greatly complicated by the widely diverse and constantly changing nature of awards available to fellows. Even under the past rules there have been many inconsistencies in the ability of fellows to apply for awards or receive travel awards. We suggest that an umbrella category be created for trainees on the approved award list that would allow them to receive money toward travel to conferences, workshops, and other activities related to their professional development.

The application of stringent rules to this junior category of workers at the NIH does not appear to have any positive impact but rather several potential detrimental effects to fellows and the ability of NIH training programs to recruit and train high-caliber fellows for future placement in respected scientific centers. We therefore request that the proposed regulations are refined in a manner that mitigates the adverse consequences for the fellows.

We look forward to working with everyone concerned to create solutions that are reasonable, equitable, and allow the NIH to focus on its mission of fostering excellence in its fellows. ■

Historically Interesting Conflicted Cartoon



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